IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

REPLY IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE SUZANNE PARISIAN, M.D.

Defendants hereby submit their Reply in Support of Defendants' Motion to Exclude Suzanne Parisian, M.D. (Doc. No. 2079 (Mot.); Doc. No. 2080 (Mem. in Support)).

I. Plaintiffs fail to specify the topics upon which Dr. Parisian purportedly will not testify.

Plaintiff's Response (Doc. No. 2148) criticizes Ethicon for moving to exclude "illusory" topics and "opinions that Dr. Parisian overtly states she *will not* offer." Pl. Resp. at 4 (emphasis in original). There are two fundamental problems with Plaintiff's contention.

First, it is notable (and suspicious) that Plaintiffs do not actually specify or confirm those topics upon which Dr. Parisian will not seek to opine. Ethicon—and the Court—are thus left to guess what the parameters of her intended testimony actually will be.

Second, in related fashion, Ethicon would be more than happy to accept Plaintiffs at their word—i.e., that there are opinions that Dr. Parisian says she will not offer, albeit unspecified, and that she will not in fact try to offer them. Yet prior experience, and decisions of federal courts across the country, confirm that if left unchecked, Dr. Parisian will seek to far exceed the

bounds of her qualifications or any sufficiently reliable methodology. *See, e.g., In re Trasylol Prods. Liab. Litig.*, 709 F.Supp.2d 1323, 1351 (S.D. Fla. 2010); *Deutsch v. Novartis Pharms. Corp.*, 768 F. Supp.2d 420, 467 (E.D. N.Y. 2011) ("The Court finds that the Plaintiffs' assertion that Dr. Parisian does not offer such opinions to be disingenuous.").

II. Dr. Parisian claims that she will *not* testify on medical causation—but Plaintiffs nevertheless argue that she is qualified to do so and offers a reliable methodology. She is not and does not.

There is no better example of the problems in limiting Dr. Parisian's anticipated testimony than with medical causation and related scientific testimony (e.g., product development, risks, design, testing, manufacturing, studies, or the standard of care for treating physicians).

On this issue, Plaintiffs' Response is inherently contradictory. On one hand, Plaintiffs ignore that Dr. Parisian stated in her expert reports, *and* testified under oath, that she would not offer any general or specific causation opinions, inter alia. *See also* Pl. Resp. at 5. But on the other hand, Plaintiffs' Response then devotes several pages' worth of argument to claim that Dr. Parisian purportedly is qualified and her opinions are reliable. *Compare* Defs.' Mem. in Support (Doc. No. 2080) at 5, *with* Pl. Resp. at 4-6.

If there were any question about Dr. Parisian's clandestine intent to opine on scientific testimony (including research, product or study design, medical causation, risks, etc.), it is confirmed by review of her proffered opinions in both of her expert reports:

PROLIFT +M
OPINION #1 – ETHICON'S DOCUMENTS AND ACTIONS HAVE DEMONSTRATED CORPORATE WILLINGNESS TO PERMANENTLY IMPLANT INVESTIGATIONAL NEW MEDICAL DEVICES IN AMERICAN WOMEN BEFORE OBTAINING 510K CLEARANCE AND **WITHOUT ADHERING TO SAFEGUARDS ESTABLISHED FOR CONDUCTING ETHICAL MEDICAL RESEARCH**. (PM Rep. ¶¶77-99).
OPINION #2: ETHICON MARKETED PROLIFT PROCEDURE KITS IN THE UNITED

STATES FOR TVM POP **BEFORE ADEQUATE STUDY DESIGN OR TESTING** AND WITHOUT FDA'S 10K CLEARANCE. ETHICON MARKETED BOTH PROLIFT/PROLIFT+M FOR TVM POP WITHOUT COMMITMENT TO CONDUCT ROBUST POST-MARKET SURVEILLANCE. AS RESULT OF ETHICON'S ACTIONS PROLIFT/ PROLIFT+M WERE MARKETED TO SURGEON'S THROUGH ITS OWN SALESFORCE FOR TVM POP WITH INADEQUATE INSTRUCTIONS FOR USE AND WARNINGS. (PM Rep. ¶¶100-121).

OPINION #9 - ETHICON MARKETED PROLIFT SYSTEMS **WITHOUT ADEQUATE STUDY TESTING OR FOLLOW-UP** TO LEARN THE **CLINICAL CONSEQUENCES FOR PATIENTS OF MANUFACTURING CHANGES** INTRODUCED FOR PROLIFT/PROLIFT +M SYSTEMS. (PM Rep. ¶¶229-241).

OPINION #10 - ETHICON'S MARKETING FAILED TO WARN PHYSICIANS THAT IT HAD **NOT STUDIED THE SHORT- AND LONG-TERM RISKS, CHANGES IN TISSUE INGROWTH, PROPERTIES OF HEALING, INFLAMMATION, NAMELY CLINICAL CONSEQUENCES** FOR WOMEN OF THE AMOUNTS OF ABSORBABLE POLIGLECAPRONE IMPLANTED BY PROLIFT+M MESH DURING PFR. (PM Rep. ¶¶242-254).

TVT-S

OPINION #1 - ETHICON's 510(K) FAILED TO **ADEQUATELY DESCRIBE A FULL AND ACCURATE DISCLOSURE OF THE MANY SIGNIFICANT DIFFERENCES** BETWEEN TVT-SECUR (A NEW SIS MINI TAPE) AND THE TVT AND TVT-O SYSTEM PREDICATES ORIGINALLY CITED BY ETHICON. ETHICON **FAILED TO DESCRIBE RISKS** ASSOCIATED WITH THE DEVICE PRIOR TO CLEARANCE. DESPITE THE **FORESEEABLE AND UNANSWERED RISKS** REMAINING FOR IMPLANTING WOMEN WITH A NEW MINI SLING, ETHICON WAS ABLE TO REFERENCE GYNE IDEAS' MINI TAPE DEVICE AS A PREDICATE AND AVOID OBTAINING CLINICAL DATA PRIOR TO 510(K) CLEARANCE.

OPINION #2 - ETHICON **KNEW THERE WERE NEW RISKS** FOR SIS MINI SLING WHEN COMPARED TO TVT AND TVT-O SYSTEMS BASED ON CHANGES MADE TO HELP REDUCE COSTS. HOWEVER, ETHICON CHOSE NOT TO **STUDY THE IMPACT** OF THOSE CHANGES FOR PATIENT SAFETY. ETHICON DID NOT UPDATE ITS TVT-SECUR IFU TO **ADEQUATELY WARN OF INCREASED RISKS** FOR PREMATURE FAILURE, CHRONIC PAIN, DYSPAREUNIA, MESH EXTRUSION AND EROSION, CHRONICITY AND WORSENING OF SYMPTOMS, DIFFICULTIES WITH MESH REMOVAL, DIFFICULTIES WITH INSERTER FUNCTION AND PATIENT NEED FOR ADDITIONAL SURGERY.

OPINION #3 - ETHICON, DESPITE HAVING MADE SPECIFIC ASSURANCES TO ITS OWN MEDICAL INVESTIGATORS THAT CERTAIN ADDITIONAL **SAFETY STUDIES** WOULD BE PERFORMED DID NOT LIVE UP TO THAT AGREEMENT.

OPINION #4 - ETHICON'S MARKETING FOR TVT-S TARGETED SURGEONS WITHOUT REGARD AS TO PELVIC SURGERY EXPERIENCE, MINIMIZING DIFFICULTIES FOR PLACEMENT OF THE MINI SLING, INACCURATELY CALLING IT 'LESS INVASIVE' WHILE KNOWING THE PROCEDURE HAD A SIGNIFICANT SURGEON LEARNING CURVE, THE 'U' APPROACH WAS HARDER TO PERFORM THAN THE 'HAMMOCK', DIFFICULTIES WERE REPORTED WITHDRAWING THE INSERTER WITHOUT DISPLACING THE MINI SLING. ETHICON SELECTIVELY PROVIDED SOME SURGEONS WITH UPDATED INSTRUCTIONS AND SURGICAL TIPS WHILE ETHICON FAILED TO ADEQUATELY UPDATE ITS OWN LABEL, IFU AND MARKETING AND SALES FORCE TO WARN 'ALL' SURGEONS EQUALLY OF TVT-SECUR INCREASED RISKS COMPARED TO OTHER TREATMENT OPTIONS FOR SUI. FINALLY, ETHICON FAILED TO WARN SURGEONS ABOUT PATIENT RISKS FOR MESH EXTRUSION, EROSION, CHRONIC PAIN, WORSENING OF SYMPTOMS, DYSPAREUNIA AND NEED FOR ADDITIONAL SURGERY.

OPINION #5 - DESPITE ETHICON'S KNOWLEDGE OF **POST-MARKET DIFFICULTIES FOR THE TVT-S SYSTEM** , INCLUDING HIGH FAILURE RATE, BLADDER PERFORATIONS, COMPLAINTS FROM ITS OWN TRAINED KEY OPINION LEADERS (KOL), AND THAT EUROPEAN SURGEONS HAD STOPPED PERFORMING TVT-SECUR IN 2007 BASED ON UNACCEPTABLE RISKS, ETHICON CONTINUED TO MARKET TVT-SECUR IN THE UNITED STATES WITHOUT NOTIFYING SURGEONS OR PATIENTS ABOUT THE INCREASED RISKS. ETHICON DID NOT VOLUNTARILY CONDUCT POST-MARKET SURVEILLANCE STUDIES INCLUDING THE 522 STUDY IN ORDER TO UPDATE ITS AMERICAN LABEL, PHYSICIANS AND WOMEN WITH ACCURATE RISK INFORMATION.

OPINION #6 - BASED ON ETHICON'S MISREPRESENTATIONS TO ITS SALES FORCE AND PHYSICIANS AS WELL AS THE FDA, INCLUDING ITS FAILURE TO CONSIDER AND DISCLOSE THAT THE MOST EXPERIENCED SURGEONS WITH TVT-S EXPERIENCED DIFFICULTIES AND PREMATURE FAILURES WITH THE DEVICE, IMPLANTING SURGEONS WOULD NOT HAVE BEEN ABLE TO PROVIDE PATIENTS WITH AN ADEQUATE INFORMED CONSENT BASED ON **KNOWLEDGE OF THE RISKS** OF THE TVT-S PRODUCT AS A SIS MINI SLING FOR SUI

OPINION #7 - SURGEONS RELIED ON THE KNOWLEDGE, SKILL AND EXPERIENCE OF ETHICON AS A MAJOR UNITED STATES MEDICAL DEVICE MANUFACTURER TO ADEQUATELY INFORM THEM OF THE **RISKS FOR THE TVT-S AND PROVIDE PHYSICIANS WITH SAFE AND EFFECTIVE PRODUCTS** TO PERMANENTLY IMPLANT IN WOMEN.

See Exhibits C and D to Defs.' Mot. (Prolift + M Expert Report and TVT-S Expert Report, respectively). These proffered opinions—literal excerpts from Dr. Parisian's actual expert

reports—show the fallacy of Plaintiffs' contention that Ethicon has "attempt[ed] to recast the nature and foundation" of Dr. Parisian's opinions. *See* Pl. Resp. at 6. Far from it: Ethicon has read what Dr. Parisian has put in her expert reports and believes that to be an accurate representation of what she intends to offer.

Simply put, on the issue of scientific/medical testimony, Plaintiffs cannot have it both ways. Either Dr. Parisian intends to opine on this type of highly scientific testimony or she does not. It certainly appears—despite Dr. Parisian's statements and testimony to the contrary—that she intends to delve deeply into these topics.

If Dr. Parisian does attempt to offer medical or scientific testimony, the Court should exclude such any opinions because she is not qualified and her opinions are not founded on reliable methodology. Plaintiffs argue that Dr. Parisian's "regulatory expertise" encompasses topics such as "product development, risks, design, testing, manufacturing, [and] studies." Pl. Resp. at 5. Not surprisingly, Plaintiff does not cite to a single piece of evidence to support the outlandish notion that "regulatory expertise" qualifies Dr. Parisian to become a jack-of-all-trades expert on all topics relating to pelvic mesh. Nor have other federal district courts fallen for this bait. *See* Defs.' Mem. at 7-8 (collecting cases where courts have excluded Dr. Parisian on this basis, including *Stambolian v. Novartis Pharms. Corp.*, 2013 WL 6345566, *9 (C.D. Cal. Dec. 6, 2013): "Dr. Parisian is not permitted to testify to things outside of her expertise. This includes testimony that may be couched as regulatory causation but in actuality speaks to medical causation. Dr. Parisian is not qualified to testify to the causal connection" between the products and alleged injury)).

Moreover, Plaintiffs' attempt to argue that Ethicon only challenged Dr. Parisian because she had not treated a patient in 30 years, Pl. Resp. at 5-6, is inaccurate. Even a cursory review of

Ethicon's brief reveals that her lack of clinical experience is only one of many shortcomings that render Dr. Parisian unqualified on these issues. Plaintiffs do not, and indeed cannot, dispute the following facts regarding Dr. Parisian's qualifications and lack of any methodology in arriving at her opinions:

- She has never performed surgery to treat pelvic organ prolapse;
- She has never participated in any animal or cadaver studies regarding any mesh;
- She has never designed mesh;
- She has never done any biomechanical testing or lab work of mesh;
- She has never done any lab work regarding mesh;
- She has never tested a polypropylene or mesh explant;
- She has never inspected or even looked at a mesh explant of any kind under a microscope, and she has never seen the product implanted, watched a video, held the device, or been in the same room as the product;
- She had never heard of the products until asked to look at it for litigation;
- She has no idea how many of the devices have been implanted in the United States or the world.
- She never worked on any mesh products during her four-year position at FDA;
- She has never spoken with a physician who has implanted the device or read the deposition of any physician who has implanted the device;
- She does not know if there is medical literature that implanting physicians should read;
- She does not know what the medical community knew at pertinent times regarding the product in question: for instance, she does not know whether the medical community knew of chronic dyspareunia, chronic pain, vaginal scarring, urinary problems, organ/nerve damage, bleeding/wound complications, inflammation, fistula formulation, neuromuscular problems, need for additional surgeries, or risks of erosion, exposure, extrusion, contraction, or shrinkage.

See Defs.' Mem. at 5-9, 15-19, 21-24.

Not only does Dr. Parisian confess this lack of knowledge to support her wide-ranging opinions—Plaintiffs' Response does not even attempt to address these shortcomings. Instead, Plaintiffs try to fall back on Dr. Parisian's stint at the FDA to make her an expert in all things. She is not. *See, e.g., In re Trasylol Prods. Liab. Litig.*, 709 F. Supp.2d 1323, 1337 (S.D. Fla. 2010) ("Dr. Parisian is neither a causation expert nor an epidemiologist," and "[w]hile Dr. Parisian's Report contains many opinions on the findings of scientific studies related to Trasylol and the association of Trasylol with various health risks, the Report alone did not allow me to conclude with certainty whether Dr. Parisian's experience at the FDA qualifies her to make such opinions . . . ."). Because Dr. Parisian is unqualified, and her opinions are not based on a reliable methodology, any opinions on medical or scientific testimony should be excluded.

III. Plaintiffs first concede, then try to salvage, Dr. Parisian's "state of mind" opinions, but they are inadmissible.

Like the arguments above, Plaintiffs' Response both giveth and taketh away regarding Dr. Parisian's regulatory opinions and "state of mind" testimony. The response begins by conceding that "Plaintiffs will comply with this Court's prior rulings and will not elicit testimony from Dr. Parisian on Defendants' state of mind, motive, or intent." Pl. Resp. at 7. Almost in the same breath, however, the response delves into why (in Plaintiffs' estimation) Dr. Parisian's testimony will not be subject to exclusion after all, claiming that this testimony is "not necessarily" "state of mind" testimony. *Id*.

Again, review of Dr. Parisian's expert opinions—as she herself drafted them—belie the notion that Dr. Parisian will "not necessarily" drift into inadmissible territory. To the contrary, her opinions are replete with commentary on Ethicon's "corporate willingness," lack of "commitment to conduct[ing] robust … surveillance," management decision to discontinue sales

rather than obtain information about the product for doctors and patients, and failure to adhere to the "company's code of conduct to conduct business with integrity and do the right thing . . . ." (emphasis added):

PROLIFT +M
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THOSE CHANGES FOR PATIENT SAFETY. ETHICON DID NOT UPDATE ITS TVT-SECUR IFU TO ADEQUATELY WARN OF INCREASED RISKS FOR PREMATURE FAILURE, CHRONIC PAIN, DYSPAREUNIA, MESH EXTRUSION AND EROSION, CHRONICITY AND WORSENING OF SYMPTOMS, DIFFICULTIES WITH MESH REMOVAL, DIFFICULTIES WITH MESH REMOVAL, DIFFICULTIES WITH INSERTER FUNCTION AND PATIENT NEED FOR ADDITIONAL SURGERY.

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Dr. Parisian clearly intends to tell the jury her beliefs about Ethicon's knowledge, its state of mind, and whether it acted reasonably. This is impermissible expert opinion. As one federal court has observed, "[m]yriad other courts have observed and excluded this type of testimony in Dr. Parisian's reports in the past." *See* Defs. Mem. at 10 (collecting cases; citation from *Lopez v. I-Flow Inc.*, 2011 WL 1897548, *11 (D. Ariz. Jan. 26, 2011)).

IV. Dr. Parisian's report consists of "narrative" regulatory opinions that courts routinely reject.

Regarding impermissible narrative testimony, Plaintiffs cite to prior rulings of this Court permitting what they characterize as similar testimony. Pl. Resp. at 7-9. Notably missing from Plaintiffs' Response is *any* citation to Dr. Parisian's reports, or deposition testimony, to explain why and how *her* testimony here is admissible. *Id*. The Court is left only with Plaintiffs' promise that Dr. Parisian will not embark on an impermissible narrative. The absence of any support—by Plaintiffs, who are the proponent of Dr. Parisian's testimony and bear the burden to establish its admissibility—is particularly notable, especially when juxtaposed against the legion of courts excluding Dr. Parisian because she offered a "regurgitation of facts." *See* Defs.' Mem. at 13-14 (collecting cases specifically excluding Dr. Parisian on these grounds).[1]

V. Plaintiffs' argument on "post-market vigilance" is not responsive to the pending motion and, in any event, Plaintiffs concede such testimony is irrelevant and will not be offered by Dr. Parisian.

Plaintiffs offer an argument in their Response regarding "Dr. Parisian's opinion that Ethicon failed to comply with applicable post market vigilance." Pl. Resp. at 9-10. It is unclear what Plaintiffs are referring to or how this is responsive to any argument in Ethicon's motion. If Plaintiffs mean to respond to the argument that Dr. Parisian may not offer legal conclusions, they are incorrect as a matter of well-settled law. *See* Defs.' Mem. at 11-13. In any event, Plaintiffs concede that such information is "admittedly irrelevant and will not be offered at trial." Pl. Resp. at 10. Any such testimony should be excluded.

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[1] The state court testimony by Dr. Parisian attached to Plaintiffs' Response (Pl. Resp. at Ex. 1) illustrates this point. It consists of hours' and hours' worth of narrative testimony by Dr. Parisian. That testimony also, overwhelmingly, was about the FDA's 510(k) clearance process, which this Court has excluded in prior mesh cases.

VI. Dr. Parisian is not qualified to opine on foreign regulatory matters; her testimony is not based on a reliable methodology; and these opinions would not be helpful to the jury.

Plaintiffs' Response offers precious little to conclude that Dr. Parisian's "considerable experience renders her qualified" to offer opinions about foreign regulatory matters. Instead, they simply state that Dr. Parisian will "only" opine on "global regulatory standards." In so arguing, Plaintiffs cite to a single paragraph from Dr. Parisian's 99-page report, which purportedly "explains in detail" her "unique qualifications to opine on foreign regulatory matters, including practical application of global industry standards:" (Pl. Resp. at 10):

> 18. Over the course of my career, I have been an integral member as a regulatory consultant for multiple companies and review teams, where together we determined whether the products would be sufficient to meet FDA's regulatory requirements and global industry standards. As part of this analysis, I would consider whether additional studies/testing was required, and, if additional studies/testing was required, what types of studies/testing were necessary. Additionally, I determined whether the proposed device label, labeling, instructions for marketing was adequate and all-encompassing for the provider according to the various industry and regulatory standards and my training and experience. For example, in my post-market role as the Medical Officer in OHA, I was required to provide FDA's official comments and participate with various international and national industry groups to help develop industry standards' for FDA-regulated medical devices. Since leaving the FDA there were many years when I continued to be a regulatory and medical expert on industry standard committees involved with design, development and critique of various types of voluntary medical device industry standards. I have often been asked to evaluate the types of proposed testing/studies for a manufacturer as related to industry standards for manufacturing and clinical trials needed to obtain patient data and update labeling and marketing and training even when clinical studies were not required under FDA's guidelines to obtain 510(k) clearance. I have utilized clinical trials and studies (clinical data) to inform companies and physicians about the risk/benefit ratio of a particular product or types of products, which assisted them in the creation and updating of IFUs, training materials, methods for risk management and updating of marketing materials, which had to be consistent with both the potential risks and benefits of a new or marketed device or product and FDA's pre-market clearance (approval) and intended use. I have presented on US medical devices to foreign regulatory agencies as well as foreign medical organizations as to how products were evaluated in the United States, the use of the product in patients, labeling requirements for the FDA, as well as helping that regulated industry obtain acceptance and reimbursement by foreign regulatory agencies. I also had to have a working familiarity with United States and

> International standards and requirements to help a Sponsor harmonize its products for effective marketing both in and outside the United States.

Pl. Resp. at 10 (citing Defs.' Mot., Exh. C: Parisian PM Rep. at ¶18). A few nonspecific references to participation, presentations and/or "helping" are insufficient to deem Dr. Parisian qualified as an *expert* in foreign regulatory matters, and in any event do not amount to the as-promised "detailed explanation of her methodology on this point." Pl. Resp. at 10. Any foreign regulatory testimony should be excluded.

VII. Dr. Parisian should not be permitted to testify about the adequacy of the warnings because Plaintiffs have failed to establish that she is qualified or that has employed a sufficient methodology.

Plaintiffs' Response fails to establish that Dr. Parisian is qualified and that she employs a reliable methodology regarding product warnings. Perhaps most fundamentally, Plaintiffs mischaracterize Ethicon's arguments and citations to the record. Plaintiffs claim that Ethicon's argument "centers almost exclusively on her lack of involvement with the specific devices at issue . . ." and, further, that "[a]n expert's failure to examine a particular source of information is not grounds for exclusion under *Daubert* . . . ." Pl. Resp. at 11, 15.

Plaintiffs' argument ignores reality. It is not that Dr. Parisian is missing one small piece of an entire puzzle. Quite the contrary is true. As reiterated in the bullet-point list in Section II, *supra*, there are multiple reasons that, taken together, render her unqualified and without a reliable methodology.

Namely, it is not *only* that Dr. Parisian has no relevant medical experience with the conditions in issue; has never participated in studies regarding any mesh device; has never done any testing; has never done any testing; and has never seen the products in issue. *See* Section II, *supra*; Defs.' Mem. at 5-9, 15-19, 21-24. It is *also* that Dr. Parisian could not discern the pertinent IFU; was left to "guess" because she was "not sure which [IFU]" was which; and could

not even recall if she had seen the relevant patient brochure. *See* Defs. Mem. at 10. It is *also* that Dr. Parisian has no relevant knowledge as to the implanting physicians who would receive the warnings in the IFU because she has never spoken to any such physician, read any such deposition, or conducted any survey of to determine what the surgeons would understand from their training and experience. *See id*. at 16-17. It is *also* that Dr. Parisian has no idea about what medical literature an implanting physician should read, because "[i]t depends . . . how they learn stuff." *Id*. at 17. It is *also* that Dr. Parisian freely admitted, at her deposition, that she does not know what a surgeon reading the IFU would know. *See id*. It is also that Dr. Parisian seeks to offer an *expert* opinion on warnings, yet testified that she does not know what the pertinent risks were at the pertinent point in time. *See id*.

Plaintiffs' only additional reference—representing five pages' worth (out of hours' worth) of testimony by Dr. Parisian in a prior mesh state court case—otherwise provides no support for Plaintiffs' argument. First, in that case, the judge in fact acknowledged from the start that he had "some indication from counsel that this witness tends to go far afield. And we need to make sure and corral this witness that instead of expressing generalized opinions be based again on her expertise with FDA approval processes and federal regulations." *See* Pl. Resp. at Exhibit 1, at 21:7-12. Second, the state court did not apply the same standards as this Court with respect to proper scope of expert testimony on federal regulations and compliance with FDA processes. *Compare id*., *with* Defs.' Mot. at 11-13. Third, that court acknowledged that Dr. Parisian should be limited with regard to the labeling as to "whether or not that is information that should have been provided to the physicians." Pl. Resp. at Exhibit 1, at 21:13-20. In this case, as explained in Ethicon's opening brief and not rebutted by Plaintiffs, Dr. Parisian does not have the fundamental understandings necessary to provide *expert* opinions on the warnings. Dr. Parisian

cannot be permitted to tell a jury what should have been in the product warnings to make them accurate when she herself has no knowledge of what the risks actually were.

Dr. Parisian's failure to account for what the intended users of the products already know is critical and demands exclusion of her testimony. It is a well-known common law principle that there is no duty to warn of risks already known by the foreseeable user of the product. *See also* RESTATEMENT (SECOND) OF THE LAW OF TORTS §§388(b), 402A, cmt. j.[2] This also consistent with the FDA's regulations. *See* 21 C.F.R. §801.109(c) (manufacturer need not warn of risks "commonly known to practitioners licensed by law to use the device"). This failure to account for the intended users' knowledge renders Dr. Parisian's methodology flawed and unreliable. *See Calisi v. Abbott Labs*, 2013 U.S. Dist. LEXIS 139257, *26 (D. Mass. Sept. 27, 2013) (excluding regulatory expert's opinion about sufficiency of warnings because "[w]ithout knowing the baseline of what information is needed, it is not possible to opine

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[2] *See also, e.g.*, 2-12 Frumer and Friedman, PRODUCTS LIABILITY §12.07[1][a] (2016); N.J. Stat. Ann § 2A58C:4 (1987) ("[a]n adequate product warning or instruction is one that . . . communicates adequate information on the dangers and safe use of the product, . . . taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician"); Conn. Gen. Stat. § 52-572q (b)(2) (2008) (factor to be considered in determining whether warning required is "the ability of the product seller to anticipate that the expected product user would be aware of the product risk, and the nature of the potential harm"); Kan. Stat. Ann. § 60-3305 (2007) (no duty to warn about risks "which a reasonable user or consumer of the product, with the training, expertise, experience, education and any special knowledge the user or consumer did, should or was required to possess"); *Brooks v. Medtronic, Inc*., 750 F.2d 1227, 1230 (4th Cir. 1984) (no duty to warn of characteristics "well known to the medical community"); *Guevara v. Dorsey Labs.*, 845 F.2d 364, 367 (1st Cir. 1988) (summary judgment for defendant based on "the general level of knowledge existent in the target [medical] community"); *Huskey v. Ethicon, Inc.*, No. 2:12-CV-05201, 2015 WL 4944339, at *7 (S.D. W. Va. Aug. 19, 2015) ("The medical device manufacturer, however, need not warn about 'risks already known to the medical community'") (Illinois law) (citation omitted); *Carlin v. Superior Court*, 920 P.2d 1347, 1354 (Cal. 1996) ("a pharmaceutical manufacturer may not be required to provide warning of a risk known to the medical community"); *Zachary v. Dow Corning Corp.*, 884 F. Supp. 1061, 1065 (M.D. La.1995) ("the duty to warn in the learned intermediary context requires an adequate warning of inherent dangers not within the knowledge of or obvious to the average learned intermediary").

meaningfully on the information's adequacy for [physicians]"). Further, her opinions are inconsistent with the legal standard to be applied by the jury, and therefore do not fit this case. *See In re Welding Fume Prods.*, 2005 WL 1868046, at *7 (N.D. Ohio Aug. 8, 2005) (excluding expert's opinion regarding adequacy of the warning because the incorrect standard applied by the expert "does not necessarily translate to a legal warning requirement, nor does it necessarily imply liability").

And finally, to the extent Plaintiffs claim that Dr. Parisian instead intends to opine on whether the labeling was false and misleading (as opposed to "inadequate"), that argument fails because such opinions are irrelevant and not the proper subject of expert testimony. *See* Defs.' Mem. at 11-15.

VIII. Plaintiffs do not contest the inadmissibility of any opinions regarding LifeScan.

Ethicon's Motion to Exclude explained that Dr. Parisian's expert report contains several paragraphs on a regulatory action against Johnson & Johnson involving LifeScan products, and that any testimony on this is irrelevant and inadmissible. *See* Defs. Mem. at 25. Plaintiffs did not respond to this argument and thus concede that Dr. Parisian may not offer any opinions on any product other than the Prolift + M or TVT-Secur.

In conclusion, as set forth in Ethicon's opening motion and memorandum in support and as discussed above, Dr. Parisian should be excluded from testifying in any capacity in this litigation. Ethicon prays for all other relief to which it is entitled.

Respectfully submitted,

/s/ Christy D. Jones
Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010

Ridgeland, MS 39158-6010
(601) 985-4523
christy.jones@butlersnow.com

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1807
dthomas@tcspllc.com

COUNSEL FOR DEFENDANTS
ETHICON, INC. AND JOHNSON & JOHNSON

CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones